

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA; the States of  
CALIFORNIA, COLORADO, CONNECTICUT,  
DELAWARE, FLORIDA, GEORGIA, HAWAII,  
ILLINOIS, INDIANA, LOUISIANA,  
MARYLAND, MASSACHUSETTS, MICHIGAN,  
MINNESOTA, MONTANA, NEVADA, NEW  
HAMPSHIRE, NEW JERSEY, NEW MEXICO,  
NEW YORK, NORTH CAROLINA,  
OKLAHOMA, RHODE ISLAND, TENNESSEE,  
TEXAS, VIRGINIA, and WISCONSIN; the  
DISTRICT OF COLUMBIA, the CITY OF  
CHICAGO, and the CITY OF NEW YORK *ex rel.*,  
and OSWALD BILOTTA,

Plaintiffs,

-against-

NOVARTIS PHARMACEUTICALS  
CORPORATION,

Defendant.

**11 Civ. 0071 (PGG)**

**DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION'S  
RESPONSE IN OPPOSITION TO THE UNITED STATES OF AMERICA'S  
MOTIONS IN LIMINE**

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Defendant Novartis Pharmaceuticals Corporation (“NPC”) submits this response in opposition to 14 motions in limine (“MIL”) filed by plaintiff United States of America (the “Government”) to exclude certain evidence that it believes NPC may seek to introduce at trial and to establish the admissibility of certain evidence that the Government intends to introduce. For the reasons set forth below, the Court should deny the Government’s motions on their merits or, in the instances where NPC does not intend to offer the challenged evidence, as moot.

### **ARGUMENT**

#### **1. The Government’s MIL #1—To Exclude Evidence and Argument Regarding Impact on Incremental Prescribing—Should Be Denied**

The Government has moved in limine to preclude evidence and argument regarding whether incremental prescriptions were written by doctors as a result of its alleged kickback scheme—evidence and argument that up to now have been a part of the Government’s own case, including its expert opinions. According to the Government, such evidence and argument are irrelevant because it does not need to prove causation at trial and are “unfairly prejudicial”, notwithstanding that the Government has already developed expert opinions and fact evidence on the same topic it now seeks to exclude. See Gov’t MIL at 2-7. As set forth in its pretrial memorandum of law, NPC disagrees with the Government’s view of the law regarding causation and, in any event, believes this evidence is highly probative, not only for establishing proximate causation, but also for establishing whether there were kickbacks in the first place and whether NPC had the requisite intent. The Government also contends that “having argued and persuaded the Court that pre-2002 doctor information—critical to reliably calculate doctors’ hypothetical but-for prescribing—was unnecessary in this case, Novartis should be

estopped from now putting forward an argument that cannot be adequately rebutted without this information it refused to produce”. Id. at 3. This argument ignores that (a) NPC opposed the Government’s 2015 request not on relevance grounds, but because the 10 years of data already produced was sufficient to identify trends; and (b) the Government’s expert agreed, not even mentioning the lack of 2001 data as an issue in his report.

A. Evidence of Incremental Prescribing Is Relevant and Highly Probative with Respect to Causation

For the reasons set forth in NPC’s pretrial memorandum of law, the Government is wrong that to recover damages on its FCA claims it need not establish that the alleged kickbacks induced doctors to write prescriptions; as such, this evidence is relevant and highly probative. In its motion, the Government relies heavily on United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89 (3d Cir. 2018), which held that the “resulting from” language in Section 1320a-7b(g) of the AKS does not require a showing of “but for” causation to establish “falsity” under the FCA. See id. at 96-97; see also 42 U.S.C. § 1320a-7b(g) (stating claims are “false” only when they “include[] items or services resulting from a violation of” the AKS). Contrary to what the Government contends, however, NPC does not argue that the law requires but-for causation, only proximate causation—i.e., the Government must prove that the kickback had a substantial contributing impact on a doctor’s prescribing decisions. In other words, NPC does not believe the Government must show that a doctor would not have prescribed the medication “‘absent the kickbacks’”, Greenfield, 880 F.3d at 98, but rather that the kickback had a substantial influence; the amount of that influence—the incremental prescriptions—is the Government’s damages, if any. See, e.g., Def.’s

Pretrial Mem. at 15-16; Def.’s Req. D-21 (False Claims Act: ‘Proximate Causation’ Required); Def.’s Req. D-27 (Measure of Damages); United States v. Luce, 873 F.3d 999, 1014 (7th Cir. 2017) (“our own reading of the statutory language now convinces us that the course charted by our sister circuits is the correct reading of the statutory text . . . and adopt the proximate cause standard for FCA cases”). To assess whether a kickback had any influence and to determine any resulting damages, trends in doctors’ prescription writing during the period of the alleged kickbacks is highly probative.

Greenfield’s analysis is also incomplete with respect to parties, like NPC, that did not directly present a claim, as the pharmacy defendant did in Greenfield. Although NPC disagrees that the Third Circuit correctly interpreted the “resulting from” language for purposes of falsity, the Government here is relying on an additional element of the FCA—the “cause[d] to be presented” prong—which by its explicit terms incorporates causation. See 31 U.S.C. § 3729(a)(1)(A). As discussed in NPC’s pretrial memorandum of law, and as Judge McMahon recognized in United States v. Teva Pharm. USA, Inc. (“Teva II”), the “caused to be presented” language requires proximate causation. No. 13-cv-03702, 2019 WL 1245656, at \*25-27 (S.D.N.Y. Feb. 27, 2019). Although Judge McMahon rejected Teva’s argument that proximate causation is the same thing as “but for” causation—something NPC does not argue—she recognized that a “chain of causation” must be proven at trial and could be broken by, for instance, independent medical judgment.<sup>1</sup> Id. at \*26-27. Judge McMahon also noted that although

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<sup>1</sup> Although NPC believes that Teva II correctly held that causation is required, NPC respectfully contests the court’s suggestion that the burden of proof shifts to the defendant to prove breaks in the chain of causation. Id. at \*27. The Government has the burden of proof on each element of its claims, including causation.

the plaintiffs in Teva II “raised an inference of causation . . . that a jury may use to find liability”, without direct evidence that the alleged kickbacks increased prescriptions, it was not “the strongest one”. Id. Thus, Teva II, at minimum, confirms the relevance of this evidence at trial for the jury to assess. Judge McMahon’s decision earlier this month denying Teva’s motion for interlocutory appeal does the same: “The Court agrees with Relators that the ‘the interests of judicial economy are served by having the parties present all of their evidence at trial (including all evidence regarding causation).”’ No. 13-cv-03702 (S.D.N.Y. Apr. 11, 2019), ECF No. 181 (emphasis added).

Here, by contrast, the Government seeks to benefit from an inference of causation, without actually having to put that inference before the jury to assess. For example, in its pretrial memorandum of law, the Government states that “the kickback creates the very real possibility that the recipient’s medical decisions were not based entirely on his or her independent medical judgment, but (in whole or in part) on the kickback”. Gov’t Trial Mem. at 4 (emphasis added). Similarly, the theory of damages the Government has repeatedly espoused rests on the notion that it did not get the benefit of its bargain—i.e., “that the doctors who wrote the prescriptions were conflict-free and making prescribing decisions based solely on medical needs and not financial considerations”. E.g., Gov’t Opp’n Mot. Summ. J. 36, 43; see also Gov’t MIL at 10. Evidence that doctors did not, in fact, increase their prescriptions in response to the alleged kickbacks is highly probative that doctors made prescribing decisions “based solely on medical needs” and directly undercuts the inferences the Government is attempting to draw. Consistent with Judge McMahon’s rulings in Teva, the Court should



reject the Government's attempt to have it both ways: to benefit from an inference of "taint" and exclude evidence to the contrary.

B. Evidence of Incremental Prescribing Is Relevant and Highly Probative with Respect to Other Elements of the AKS/FCA Claims

Independent of causation, evidence of whether NPC's speaker events increased doctors' prescriptions is also probative of whether NPC actually paid kickbacks in the first place; it undermines the Government's claim that these events were, in fact, bribes designed to induce prescriptions if doctors did not actually increase prescriptions as a result of the events. Evidence of incremental prescribing similarly is relevant to NPC's state of mind; it undermines the Government's allegation that NPC knowingly and willfully paid "hundreds of millions of dollars of kickbacks to doctors . . . for the purpose of inducing those doctors to prescribe NPC drugs", Gov't Trial Mem. at 1, if NPC did not receive incremental prescriptions from the alleged scheme.

The Government itself has repeatedly recognized the significance of a kickback's influence on doctors. See, e.g., Gov't Trial Mem. at 4 ("A kickback eliminates th[e] assurance [that medical care is conflict-free] because it taints the kickback-recipient's medical decisions with financial interest. . . . [K]ickbacks are designed to influence providers' independent medical judgment in a way that is fundamentally at odds with the functioning of the system as a whole" (internal quotation marks omitted)). For this reason, NPC should be permitted to provide the jury with testimony from doctor witnesses who expressly stated during their depositions that they had not increased their prescriptions in response to the speaker events as part of making the larger points that those events could never have influenced their prescribing and that they would never have engaged in kickback activity. See, e.g., Decl. of Benjamin

Gruenstein Resp. Opp'n Pls.' MILs ("Gruenstein Opp'n MIL Decl."), Ex. 1 (Tr. Dr. Ivins 26:8-22, 94:15-20, 117:20-118:14, 120:25-121:23, 183:22-184:8), Ex. 2 (Tr. Dr. Ismail 69:2-22, 139:8-142:12), Ex. 3 (Tr. Dr. Mendez 94:6-20, 164:6-167:14). NPC also plans to introduce evidence that NPC prescriptions for certain doctors decreased after attending events that the Government alleges were kickbacks, while their non-NPC prescriptions increased. Such evidence is highly probative of whether NPC knowingly and willfully paid bribes to these doctors, independent of any causation issue.

Finally, the opinions of NPC expert Dr. Eric Gaier about incremental prescribing that the Government seeks to exclude, Gov't MIL at 2, 5, also demonstrate that NPC intended that the programs provide promotional information about NPC's medications, not bribes. See Vargas Decl., ECF No. 320, Ex. E ("Gaier Rep.") ¶¶ 26, 28 ("Regardless of whether any particular event lacked educational benefit for a given attendee, the government's kickback theory is based upon a false dichotomy that ignores a credible alternative purpose, at least as a matter of economics, for hosting doctors repeatedly at events: promotion . . . . [T]he overall pattern of diminishing (but non-zero) marginal impacts for repeated attendance is consistent with promotional wear out."), ¶¶ 102-105 ("This analysis further supports my opinion that the impacts of speaker and roundtable events that Prof. McFadden purports to identify are consistent with promotion", not kickbacks).

C. Evidence of Incremental Prescribing Has Also Been a Part of the Government's Case

Throughout fact and expert discovery, the Government has sought to develop evidence of incremental prescribing resulting from alleged kickbacks. Thus, the Government cannot now be heard to argue that NPC's analyses rebutting this evidence

“would inject new, complicated issues” into the case, Gov’t MIL at 6; and that it would be “unfairly prejudic[ed]” if it had to use the evidence it already developed, id. at 2-3, 5-6. After alleging (and attempting to lay the groundwork to prove) a complicated and technical case, the Government now seeks to ease its burden at trial by MIL; the Court should reject this improper attempt.

In particular, the Government has designated witness testimony for trial related to doctors writing more NPC prescriptions or choosing NPC drugs over those of competitors because of the alleged kickbacks. See, e.g., Gruenstein Opp’n MIL Decl. Ex. 4 (Tr. Dr. Hom 59:4-60:16, 71:23-72:14, 184:23-185:12, 187:6-188:1, 190:2-13, 195:9-16), Ex. 5 (Tr. Dr. Lake 67:6-23, 78:15-21, 94:3-12, 94:25-95:24). The Government’s expert Dr. McFadden also conducted an extensive analysis “to address whether and to what extent Novartis prescription rates among doctors have been influenced by receiving kickbacks . . . through Novartis events”. Vargas Decl. Ex. D (“McFadden Rep.”) at ¶ 8. He concluded that “[t]he kickbacks identified by the criteria caused doctors to write more prescriptions for Novartis drugs at issue than they otherwise would have.” McFadden Rep. ¶ 12. While the Government now dismisses Dr. McFadden’s damages analysis based on incremental prescriptions as an “alternative” damages model “specifically requested by the Government”, Gov’t MIL at 6, Dr. McFadden made clear in both his report and deposition that his “causality” analysis was a separate inquiry from his damages model and did not characterize it as alternative, see McFadden Rep. ¶¶ 8, 26; Gruenstein Opp’n MIL Decl. Ex. 6 (“McFadden Dep.”) 21:9-18.<sup>2</sup>

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<sup>2</sup> “Q: A little bit further down in the paragraph, you say ‘I’ve also been asked to calculate damages.’ Is your damages analysis a separate inquiry from whether and to

In any event, the fact that the Government views the damages portion of Dr. McFadden’s opinions related to increased prescribing as an “alternative” model does not make it (let alone Dr. McFadden’s separate causation analysis) irrelevant. Nor does the fact that it “is a reliable floor for the incremental impact of Novartis’s bribes, but could substantially undercount the true effect”, Gov’t MIL at 5—something Dr. McFadden could easily explain to the jury, just as he does in his report, McFadden Rep. ¶ 51, n.42. Essentially the Government’s position in its MIL (and in its separate MIL #7, addressed infra § 7) is that everything in Dr. McFadden’s actual reports is irrelevant fallback and that what is not in those reports—the Government’s new damages calculations, disclosed on April 1, 2019, as discussed in response to MIL #7—is the only analysis that is now relevant. Moreover, according to the Government, NPC should only be able to cross Dr. McFadden on his new damages figures, not the opinions in his original reports—including his separate causation opinion—or the changes in his methodology since then. This is not what Rules 402 and 403 are designed to do.

Likewise, the Government’s argument that NPC should not be allowed to introduce evidence regarding the lack of incremental prescribing because it would require “extensive and very technical testimony from Professor McFadden”, Gov’t MIL at 6-7, ignores that the Government is the party with the burden of proof and that Dr. McFadden is a Nobel-prize winning economist who should be able to handle delivering such testimony to the jury. Moreover, these are not “new . . . issues”, id. at 6, and the Government has already instructed Dr. McFadden to develop this very testimony in

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what extent Novartis prescriptions were influenced by kickbacks? A. It’s a separate inquiry but the – some steps in that inquiry used implications from the first analysis.”

recognition of its burden of proof at trial. It is, of course, the Government's choice whether to put that evidence on (and it does appear that, at least to some extent, it still intends to), but to handicap NPC's defense because the complicated and technical allegations the Government has made impose on it a high burden would be fundamentally unfair and improper.

D. NPC Should Not Be Estopped from Presenting Incremental Prescription Evidence

Finally, the Government's position that NPC should be estopped from arguing that doctors did not write incremental prescriptions after opposing the Government's 2015 motion to compel data from 2001 to aid it in identifying "trends and fluctuations of doctors' speaker-program attendance and prescriptions" is baseless. June 19, 2015, Ltr. from J. Vargas to Hon. P. Gardephe, ECF No. 126, at 4; see also Gov't MIL at 7-8. First, contrary to what the Government contends, Gov't MIL at 8, NPC did not oppose the Government's 2015 request on relevance grounds. Rather, NPC argued that the 10 years of data it had already produced to the Government was more than sufficient to identify trends and so additional discovery would be unduly burdensome. June 24, 2015, Ltr. from E. Chesler to Hon. P. Gardephe, ECF No. 128, at 4. The Court also ruled for NPC on the basis of burden, finding that the data the Government already had was sufficient to identify prescribing fluctuations. Order of July 29, 2015, ECF No. 130, at 8 ("While the Government suggests that the additional years' worth of information increases the likelihood that relevant trends and fluctuations will become clear . . . discovery 'is not boundless, and a court may place limits on discovery demands that are unreasonably cumulative or duplicative.' . . . . To the extent that trends and



fluctuations in speaker program attendance and prescription writing exist, a decade's worth of data should be sufficient to demonstrate those trends and fluctuations."").

Second, NPC's position and the Court's decision at the time that 10 years of data was sufficient to analyze fluctuations in prescription writing is confirmed by Dr. McFadden. In his reports, Dr. McFadden never mentioned the lack of pre-2002 data as an issue impacting any of his incremental prescribing opinions. He did not express concern that he "was unable to reliably calculate the incremental effect of bribes on doctor's prescribing" as the Government now contends, Gov't MIL at 7, noting only that his analysis "could result in undercounting", McFadden Rep. ¶ 51, n.42. Nor did Dr. McFadden express concern about using doctors' average prescribing in the ten-year period as a baseline for determining "whether doctors change their volume of Novartis prescriptions after receiving kickbacks", id. ¶ 47, contrary to the Government's suggestion in its motion, see Gov't MIL at 4 (citing ¶ 47). Indeed, in his rebuttal report, Dr. McFadden argued affirmatively that "[t]o show that Novartis's kickbacks increased prescriptions in the aggregate, my pooled model reliably estimates the average effect of kickbacks on new prescriptions". Vargas Decl., Ex. F. (McFadden Rebuttal Rep. ¶ 11) (emphasis added). If the Government's own expert—who was instructed to and did identify trends in prescribing—failed to complain that the lack of data from 2001 made his analyses unreliable, then there is no basis for the Government to contend now that the absence of such data caused prejudice or detriment.

**2. The Government's MIL #2—To Exclude Evidence and Argument Regarding Costs of Competitor and Generic Drugs—Should Be Denied**

Consistent with NPC's response to MIL #1 and the purpose of FCA damages "to make the government 'completely whole' for money taken from it by



fraud”, United States ex rel. Feldman v. van Gorp, 697 F.3d 78, 87 (2d Cir. 2012); see also 31 U.S.C. § 3729(a)(1), evidence concerning the incremental amount (if any) the Government paid for NPC prescriptions above what it would have paid if the prescriptions were for competitor drugs is admissible under Rules 402 and 403. The Government has never alleged that NPC’s kickbacks led doctors to write any medically unnecessary prescriptions. As such, the incremental NPC prescriptions would have been written anyway, and the only money “taken from [the Government] by fraud” is any incremental price the Government paid because a prescription was for an NPC medication as compared to another available alternative. See Feldman, 697 F.3d at 98; see also United States v. Bornstein, 423 U.S. 303, 317 n.13 (1976) (characterizing actual damages as the difference between the market value of the items the Government received as a result of the alleged fraud and the market value of the items it otherwise wanted); Def.’s Req. D-27 (Measure of Damages).

Bornstein and Feldman—the binding precedent the Government cites in its motion—support NPC, not the Government. Although the Government acknowledges that Bornstein establishes the relevance of “the difference between the market value of the [items] it received and retained and the market value that the [items] would have had if they had been of the specified quality”, Gov’t MIL at 9 (quoting Bornstein, 423 U.S. at 317 n.13), it argues that Feldman cuts the other way “when the Government has not received assets with an ascertainable value”, Gov’t MIL at 9. Unlike the grants at issue in Feldman, which had no market value equivalent and no “ascertainable value”, prescription drugs have ready market prices and reimbursement rates. 697 F.3d at 87-91. Indeed, in Feldman, the Second Circuit expressly recognized Medicare FCA cases, like

this one, that had awarded as damages only “the amount of money the government paid out by reason of the false claims over and above what it would have paid out if the claims had not been false” and distinguished them as inapplicable to the grants at issue. Id. at 90-91 (quoting United States ex rel. Doe v. DeGregorio, 510 F. Supp. 2d 877, 890 (M.D. Fla. 2007) and citing United States ex rel. Tyson v. Amerigroup Ill., 488 F. Supp. 2d 719, 738-39 (N.D. Ill. 2007)) (“In short, in each of the cases cited by the defendants [including ‘FCA claims based on Medicaid or Medicare fraud’], the government paid for a contracted service with a tangible benefit—whether it be medical care, security on mortgages, or subsidized housing—but paid too much. The government in these cases got what it bargained for, but it did not get all that it bargained for. Thus, courts treated the difference between what the government bargained for and what it actually received as the measure of damages.” (emphasis in original)).<sup>3</sup>

The Government’s damages theory in this case is that it “received nothing of value from Novartis, but rather paid a subsidy to federal health care program beneficiaries”. Gov’t MIL at 10. Consistent with Feldman’s characterization of similar FCA cases, NPC disputes that theory: the Government got what it bargained for because people insured through federal health care programs received medically necessary prescriptions, and the Government paid no more than it would have otherwise for those

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<sup>3</sup> Similarly, in United States ex rel. Longhi v. Lithium Power Techs., Inc., 575 F.3d 458 (5th Cir. 2009), which the Government cites (Gov’t MIL at 10), the Fifth Circuit distinguished the grants at issue from “standard procurement contracts where the government ordered a specific product or good”—like the Government does when paying a specific amount for a specific type of drug prescription—and indicated its damages method applied only where “the intangible benefit [to the government] is impossible to calculate”. Id. at 473.

prescriptions. NPC should be allowed to introduce this evidence to rebut a central theory of the Government's case. Nor, as discussed above and in NPC's pretrial memorandum of law, does the Government's theory that it "did not receive what it bargained for" make sense in the context of its position that it need not show the alleged kickbacks actually had some influence on doctors' decisions to write prescriptions. See id. (citing United States ex rel. Westmoreland v. Amgen, Inc., 812 F. Supp. 2d 39, 53-54 (D. Mass. 2011) (recognizing that Medicare "relies on providers to seek payment only on items or services 'reasonable and necessary for the diagnosis or treatment of illness or injury'" and so the AKS "within the context of the Medicare statute" is designed to prevent kickbacks from "influenc[ing] providers' independent medical judgment in a way that is fundamentally at odds with the functioning of the system as a whole")); see also Gov't Trial Mem. at 4.<sup>4</sup>

Likewise, the Government's argument that "by Novartis's logic, for Novartis drugs that cost less than competitor drugs on average, Novartis's bribes actually benefited the Government, and the Government should owe Novartis money" is a strawman. Gov't MIL at 11. NPC is obviously not arguing that the Government owes it

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<sup>4</sup> With respect to the other cases the Government cites for this proposition, NPC does not contest that "'men must turn square corners when they deal with the government'". Gov't MIL at 10 (quoting Rock Island, Ark. & La. R.R. Co. v. United States, 254 U.S. 141 (1920)). But Rock Island—in which the Supreme Court denied a petition challenging an assessed tax because the petitioner did not adhere to the IRS's pre-conditions to suit—has no bearing on whether the Government received what it bargained for here. The Government's other cases are also not on point. See United States ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 314 (3d Cir. 2011) (holding that implied certification theory can be basis for alleging FCA liability at motion to dismiss stage); United States ex rel. Banigan v. Organon USA Inc., No. 07-12153, 2016 WL 6571269, at \*5 (D. Mass. Jan. 20, 2016) (precluding proposed expert testimony related to "[w]hether [recipient of alleged kickbacks] believed that such kickbacks, in the end, would financially benefit Medicaid" by "lower[ing] the per-pill price" of the drug at issue).

money, just that the Government must actually be monetarily damaged to recover, consistent with the text of 31 U.S.C. § 3729(a)(1), Feldman and other case law. The Government's position, in essence, is that it can recover millions of dollars in damages without NPC being able to introduce evidence that, in fact, the Government incurred no actual losses at all. That cannot be—and is not—what the FCA or the Rules of Evidence require.

As with its previous motion, the Government's Rule 403 argument that introducing evidence of the cost of alternative drugs and trends in doctors' prescribing would require it to tackle "tremendously complex and time-consuming issues", including, among other things, "the prescribing history of each of the 20,000 doctors who received bribes from Novartis with respect to competitor drugs" is an improper attempt by the Government to evade its burden of proof. Id. at 12. Contrary to what the Government claims, these are not "new issues". Id. Rather, as the Government acknowledges, Dr. Gaier in his 2017 opening report opined on the costs of competitor drugs and dispensing fees that should be deducted from any damages, id. at 9 (citing Gaier Rep. ¶¶ 149-54); and Dr. McFadden, in addition to analyzing doctors' prescribing history as part of his initial opinions, responded to Dr. Gaier on this topic in his rebuttal report, McFadden Rebuttal Rep. ¶¶ 46-48. Neither Rule 402 nor 403 is designed to shield plaintiffs from complicated issues that are difficult to prove, especially when the parties are already prepared to address them.



3. **The Government's MIL #3—To Exclude Evidence and Argument Regarding the Quality of NPC's Drugs, NPC's Corporate Character and Patient Harm—Should Be Denied in Part**

The Government has moved in limine to exclude three categories of evidence, regarding (1) the quality of NPC's drugs, (2) NPC's corporate character and (3) the lack of patients' physical harm. For the reasons set forth below, the Government's motion should be denied on the merits as it relates to (1) and (3), and as moot as to (2), as NPC does not intend to introduce evidence that the Government seeks to preclude.

A. Quality of NPC Drugs

The Court should deny the Government's motion to exclude evidence related to the quality of NPC's medications because such evidence is relevant and admissible under Federal Rules of Evidence 402 and 403. First, as discussed above, see supra § 1, and in NPC's pretrial memorandum of law, see Def.'s Pretrial Mem. at 10-11, 13, whether doctors prescribed NPC medications based solely on their independent medical judgment or medical needs is an issue of fact for trial. The quality of NPC's drugs is directly relevant to doctors' motivations for writing prescriptions: if doctors believed that NPC drugs were effective (that is, quality medications for their patients), then it is more likely that they prescribed NPC drugs based on their independent medical judgment and not because of any alleged bribes.

Second, evidence concerning the quality of NPC medications, including their side effect profiles, is relevant to NPC's intent in conducting the programs at issue. The quality of NPC's medications was a central feature of the slide decks being presented at these programs and what motivated NPC to hold programs in the first place—that is, so that doctors would hear about the features of NPC medications. Precluding such

evidence impedes NPC's ability to explain to the jury its reasons for holding programs, and the substance of the informational and educational messages it sought to deliver to doctors at them. In addition, evidence concerning the quality of NPC drugs is relevant to whether NPC knowingly and willfully paid bribes, as such evidence makes it less likely that NPC had an incentive or need to bribe doctors to prescribe its medications.

B. NPC's Corporate Character

NPC does not intend to put in evidence that Novartis is a "good company", so in that respect the Government's motion is moot. Gov't MIL at 15. However, NPC does intend, and should be permitted, to describe what it does—it creates, develops, manufactures and sells innovative, and in many cases lifesaving, medications. The nature of the Company's business is relevant on many levels, including to provide the jury with basic background about the business, the different roles and functions of the witnesses the jury will be hearing from (such as compliance personnel, sales representatives and brand managers), the facets of the Company's compliance program and why it is important that the Company be successful in selling its medications, and therefore why the Company invests in activities like marketing and promotional programs and then tracks the success of those programs.

C. Patients Not Physically Harmed

NPC does not intend to introduce evidence that patients were not physically harmed by the medications at issue (which is true, albeit not relevant to the ultimate issues in the case). NPC also does not intend to argue that lack of physical harm to patients demonstrates that NPC is not liable for the conduct alleged in this case.



However, NPC does intend to highlight that the Government does not allege that NPC's alleged kickbacks led doctors to write any medically unnecessary prescriptions, because such evidence is relevant to damages. See supra § 2; Gov't MIL #2. As discussed above, see supra § 3.A, NPC also intends to elicit testimony from doctors about the quality of NPC medications in terms of their favorable side-effect profiles (i.e., the medications caused fewer side effects than competitors' medications). Relatedly, NPC will also make clear that the Government does not allege that patients were harmed; otherwise, the jury very likely would be confused, given that the allegations in this case involve NPC allegedly paying bribes to affect doctors' behavior. See Fed. R. Evid. 403. Of course, if the Government reverses course and does attempt to introduce evidence of patient harm, NPC reserves the right to counter that evidence at trial.

**4. The Government's MIL #4—To Admit Evidence Regarding Criminal Convictions of NPC Speakers—Should Be Denied**

In this MIL, the Government seeks “to admit evidence regarding the convictions of two doctors who served as Novartis speakers, Drs. Kevork and Adelina Vorperian, for violating the federal Anti-Kickback Statute” because those convictions are “relevant to NPC's own knowing participation in a kickback scheme”. Gov't MIL at 15. Additionally, the Government seeks to call a former NPC sales representative, Michael Contreras, to testify that “while he was employed by NPC, he organized NPC speaker events for which the Vorperians were paid—even though he knew about the convictions” and contends this evidence is relevant because “[a] reasonable juror could infer that NPC's decision to use (and pay) high-prescribing doctors who had been convicted of taking illegal kickbacks is probative of NPC's own knowing participation in a kickback scheme”. Id. at 16. Because the “probative value” of the Government's intended

evidence “is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, [and] misleading the jury”, it should be excluded from trial. Fed. R. Evid. 403.

The probative value of the convictions is minimal, at best, for three reasons. First, the kickback scheme that the Vorperians pleaded guilty to is completely distinct from the scheme the Government alleges here: it did not involve NPC, a pharmaceutical company, speaker programs or any other promotion-related activities. Rather, the husband and wife physicians were convicted of receiving approximately \$20,000 total in cash payments, representing 25 percent of the collections a medical laboratory earned for specimens that the Vorperians referred to the lab. See Gruenstein Opp’n MIL Decl. Ex. 7 (Adelina Vorperian, M.D., 11-2005-168275 (Div. of Med. Quality, Med. Bd. of Cali. Oct. 27, 2006) (Decision and Order, Ex. A ¶¶ 11-13)), Ex. 8 (Information, United States v. Vorperian, CR 05-441 (C.D. Cal. May 12, 2005), Ex. 9 (Information, United States v. Vorperian, CR 05-442 (C.D. Cal. May 12, 2005), Ex. 10, Dep. Tr. of Michael Contreras 119:16-18 (“Contreras Tr.”) (“[T]hey were receiving payments from a testing facility they were sending samples to, in order to continue using that testing facility.”).

Second, contrary to the Government’s contention that Mr. Contreras’s testimony is probative of “NPC’s own knowing participation in a kickback scheme”, it is, by its terms, probative at most only of his knowledge, not of that of the thousands of other NPC employees at issue. During his deposition, Mr. Contreras also testified that at the time he became aware of the Vorperians’ guilty pleas he had no concern or awareness that he or anyone else at NPC was engaging in illegal kickbacks or that honorarium or speaker events constituted kickbacks. Contreras Tr. 144:5-145:12. Rather, he viewed the

Vorperians' guilty pleas as unrelated to their work as speakers and invited them to subsequent events because he did not believe the pleas impacted "their knowledge as doctors or their respect within the medical community and in the area". Id. 117:12-17, 145:7-12. As such, his testimony further undermines the probativeness of the evidence the Government seeks to admit for purposes of even Mr. Contreras's knowledge, as he did not have "knowing participation in a kickback scheme"; in fact, he had no idea such a scheme even existed.

Third, the Government undercuts its own position by affirmatively arguing that this evidence will not prejudice NPC because it will not alter the overall mix of information at trial, "in view of the significant amount of other evidence the Government expects to offer concerning NPC's kickback scheme". Gov't MIL at 16. The law is clear that "the availability of other, less prejudicial, evidence on the same point ordinarily reduces the probative value of a given item of extrinsic evidence . . . . If the incremental value is slight, and the possibility of prejudice through misuse by the jury great, the court should exclude the evidence under Rule 403.'" United States v. McCallum, 584 F.3d 471, 477 (2d Cir. 2009) (quoting 2 Weinstein, Federal Evidence § 404.21 (Joseph M. McLaughlin, Ed., Matthew Bender & Co. 2009) (emphasis added)).

Here, the likelihood of "prejudice through misuse by the jury" of the convictions is great because the jury is likely to view the doctors' convictions—even though they did not involve NPC or any conduct resembling speaker programs—as evidence of NPC's culpability and afford them undue weight. This is particularly true because the exhibits the Government intends to use regarding the convictions—the Judgment & Probation/Commitment Order for each Dr. Vorperian—do not identify the

underlying conduct or, in turn, reflect how that is different than what is alleged in this case; rather, they only state that the convictions are for “Illegal Remunerations Involving Federal Health Care Programs in violation of 42 USC § 1320a-7b(b)(1) as charged in Counts 1 & 2 of the Information”. See Joint Pretrial Order, Ex. D-1, PX 391 and 392. Requiring NPC to introduce evidence to explain the particular factual predicates that led to the Vorperians’ guilty pleas to show how they differ from the conduct alleged here would not only waste the jury’s time but also lead to confusion.

**5. The Government’s MIL #5—To Exclude Testimony From Witnesses Who Were Recently Disclosed—Should Be Denied**

In preparing the Joint Pretrial Order, NPC identified 12<sup>5</sup> additional witnesses—doctors, sales representatives and sales management who organized, attended, or spoke at programs that the Government now claims were kickbacks—and disclosed those to the Government on March 4 and 25, 2019 with accompanying Rule 26 information. NPC had not previously included these specific names among the 68 witnesses it disclosed pursuant to Rule 26 (although, as discussed below, it did disclose most if not all of them through general categories in those disclosures), as the 12 did not have information relevant to the specific programs identified in the Government’s Amended Complaint. See U.S. Am. Intervenor Compl. (ECF 79-1). As the Court is aware, however, the Government changed its theory of the programs that constitute

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<sup>5</sup> The Government’s motion lists 14 witnesses, although Dr. Elizabeth Ofili was disclosed in NPC’s September 26, 2016 disclosure, and NPC has advised the Government that it no longer intends to call one of the witnesses (Steve Sokolow) at trial. Of the 12 witnesses, nine are sales representatives or management who are current employees, and thus Novartis can more easily bring them to trial than former employees who will likely not testify without being subpoenaed. And two of the three doctors are in New York City, and thus would not be as inconvenienced by testifying as out-of-state doctors.



kickbacks at least twice before NPC's disclosure of its trial witness list, and a third time subsequent to that. In preparing for trial, NPC learned that these 12 witnesses all have relevant information about programs—approximately 1,000 in total—that the Government has alleged were kickbacks. They are, thus, important witnesses for NPC. While NPC has since March 25, 2019 repeatedly offered the Government the opportunity to depose these witnesses before trial, the Government has rejected that offer and instead moved in limine to preclude their testimony. In light of this history, the Court should find NPC's disclosure of these witnesses to be "substantially justified", permit both parties to take pre-trial depositions and deny the Government's motion. See Fed. R. Civ. P. 37(c)(1).

A. The Government's Changing List of Alleged Kickback Events

During the course of this case, the Government has taken at least three different positions on what events constitute kickbacks for purposes of liability and/or damages. In its December 2013 Amended Complaint, the Government initially described a couple hundred alleged kickbacks based on speaker events and honoraria and claimed generally that NPC "held thousands of speaker programs all over the country at which few or no slides were shown and the doctors who participated spent little or no time discussing the drugs at issue. Instead, Novartis simply wine and dined the doctors at high-end restaurants with astronomical costs. . . . In connection with these speaker programs, Novartis also paid doctors additional money to attend training events on the drug, notwithstanding that many of the doctors ultimately spent little or no time discussing the drugs." U.S. Am. Intervenor Compl. ¶ 2. The Government at the time did not identify the specific kickbacks that it was alleging and indicated it still could not a

year later, in December 2014, because its investigation “[wa]s ongoing”. Vargas Decl., Ex. M at Resps. Interrogs. 9-10. The Government stated that “during discovery, it [would] identify in a reasonable fashion the Novartis events upon which it [wa]s basing its claims in this case”. Id.

The Government first did so in November 2015, a year into fact discovery, identifying 79,200 alleged sham events—significantly more than the hundreds referred to in the Amended Complaint—and 108,000 healthcare providers who were purportedly paid kickbacks. The Government also “reserve[d] its right to add or subtract events from this list as additional information [became] available”. See id. Ex. N at Resp. to Interrogs. 9 and 10. In response to a second set of NPC interrogatories, the Government in March 2016 provided its “factual bases” for identifying these approximately 79,200 events, including that (a) “inappropriate honoraria was paid in connection with the event”, (b) “the event took place on a weekend”, (c) “there were an inappropriate number of attendees at the event”, (d) “the amount spent on meals and beverages was excessive”, (e) “the event took place at a venue that was not modest or conducive to a legitimate educational event”, (f) “the event was attended by one or more healthcare providers who had attended events on the same or a substantially similar topic multiple times”, (g) “the event was predominately social in nature and/or served no legitimate educational purpose for some or all of the participants”, and (h) “the number of attendees was falsely inflated in the speaker program data”. Gruenstein Opp’n MIL Decl., Ex. 11 (3/11/2016 Gov’t Suppl. Resps. Second Set Interrogs.) at Ex. A.

After the June 2017 close of fact discovery, however, the Government in the August 2017 report of its expert Dr. Graham McMahon shifted the “factual bases” it



was relying on to identify the alleged kickbacks, using three new criteria to “identify an activity that inherently lacks educational purpose”: (a) a doctor attending three or more events regarding the same drug in the span of six months or less; (b) a doctor attending a program on a drug on which the doctor had served as a speaker within the last six months; and (c) a doctor attending three or more programs with a per-person meal spend of \$125 or more over the course of 12 months. Gruenstein Decl. Support Mot. to Preclude Experts, Ex. 7 (“McMahon Rep.”) ¶ 54. Using these criteria, another of the Government’s experts, Dr. Richard Goldberg, identified 56,641 doctors who met at least one criteria at one point in time and 182,376 trigger events. See Gruenstein Opp’n MIL Decl., Ex. 12 (Goldberg Rep.) at 23. The Government in a December 2017 supplemental interrogatory response explicitly acknowledged that the set of trigger events identified by Goldberg “supersede[d]” the ones it had previously identified. See Vargas Decl. Ex. O, at Resp. Interrogs. 9-10. The number of trigger events—i.e., purported kickbacks—changed again in Dr. Goldberg’s February 2018 rebuttal report, when the Government raised the number to 526,144, with 96,152 participating doctors, by including Lunch-n-Learns. See Gruenstein Opp’n MIL Decl., Ex. 13 (Goldberg Rebuttal Rep.); Revised Decl. of Richard E. Goldberg Supp. Gov’t Opp’n Def.’s Mot. Summ. J. ¶¶ 5, 12, ECF No. 235.

Then, on April 1, 2019, the Government changed its theory a third time (at least), stating that it would not “pursu[e] Novartis bribes provided through Lunch-n-Learns events or bribes provided to doctors who (a) received less than \$1,000 in total remuneration from Novartis or (b) were national key opinion leaders as reflected in the [certain listed] Novartis documents, except Kathleen Drinan”. Gruenstein Decl. Supp.

MILs, Ex. 6. As a result of these new exceptions to Dr. McMahon's criteria, the Government again changed the number of trigger events it was claiming as a basis for damages to approximately 154,000 with 22,000 participating doctors. See id. Exs. B and C; Joint Pretrial Order, ECF No. 315, Ex. G. And with that most recent change, NPC learned that five out of the nine doctors it had identified as trial witnesses are no longer alleged to have received kickbacks for which the Government is seeking damages. While NPC still believes these doctors have probative testimony to give, this underscores how the Government's ever-shifting case has obstructed NPC's ability to identify the specific evidence it will present to rebut the Government's claims.

B. NPC's Good Faith Approach to Disclosures During Discovery

Because it was clear from the Government's various interrogatory responses that its definition of what events constituted kickbacks could evolve,<sup>6</sup> NPC's good faith approach to its Rule 26 disclosures was to include 68 specific names based on its understanding of the Government's case at the time, including the events it knew could be at issue because they were mentioned in the Government's Amended Complaint or discovery responses. Similarly, NPC included provisions covering "[v]arious

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<sup>6</sup> See Vargas Decl., Ex. N at Resp. Interrogs. 9-10 ("The Government reserves its right to add or subtract events from this list as additional information becomes available."); Gruenstein Opp'n MIL Decl., Ex. 14 (1/25/16 Gov't Resp. NPC's Second Set of Interrogs.) at Resp. Interrog. 12 (objecting to providing the reason for including specific events and the identities of the HCPs at those events because that information "will be presented through expert analysis and/or fact depositions"), Ex. 15 (Email from C. Harwood dated 8/17/16) at 2 ("While we did produce a preliminary list of doctors and events, as we advised, these lists were and are subject to change as we obtain additional discovery, continue to review the discovery that has been produced to date and consult with our experts. Accordingly, because it is neither practicable nor appropriate for us to provide further responses to these interrogatories during fact discovery, we have not provided, and do not intend to provide, any further preliminary lists.").

members of the sales force involved in events cited in the Government’s Complaint” and “[h]ealthcare providers referenced in the Government’s Complaint” because “NPC [could not] identify these individuals by name because the Government [did] not provide[] sufficient detail in its Complaint as to the particular events or individuals in question.” Gruenstein Opp’n MIL Decl., Ex. 16 (NPC Initial Disclosures, 6/28/13) at 7. In addition, to incorporate individuals whose relevance might become clear during the course of discovery, NPC included in its disclosures a provision expressly incorporating individuals identified in the Government’s initial and amended disclosures and discovery responses. See id. Ex. 17 (NPC Supplemental Disclosures, 9/26/16) at 6 (“In addition to the individuals identified above, any individual (i) noticed for deposition by any party, (ii) identified by Plaintiffs in Plaintiffs’ initial or amended disclosures, (iii) identified by Plaintiffs in Plaintiffs’ responses to NPC’s discovery requests, or (iv) for whom a signed declaration has been produced by any party.”).<sup>7</sup> Most if not all of the witnesses who the Government contends in its motion were not previously disclosed, in fact were disclosed by virtue of this provision.<sup>8</sup>

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<sup>7</sup> The Government included a similar paragraph in its Rule 26 disclosures. See id. Ex. 18 (Gov’t Further Amended Initial Disclosures, 9/22/17) at 3 (“Any Novartis employee identified by any party in response to a discovery request in this action; Any Novartis employee included by Novartis as a document custodian or a Rule 30(b)(6) designee; Any Novartis employee whose deposition is noticed by any party; Any Novartis employee who is identified during a deposition; Any Novartis sales representative or sales manager associated with a promotional event identified in response to a discovery request in this action. Any Novartis employee who executes a declaration or who is identified in a declaration.”). In fact, the Government even went a step further and incorporated “any individuals identified by defendant [NPC] in its initial disclosures, amended disclosures, or discovery responses”. Id. at 2, n.1.

<sup>8</sup> Dr. Adam Rosenbluth, Dr. Rajeev Srivastava, Gairda Lauterbach-Hagan, Matthew Fragola, Michael Madix and Paul Silverman were disclosed “by Plaintiffs in Plaintiffs’ responses to NPC’s discovery requests”, and Dr. Randall Zusman was also listed in

### C. The Parties' Preparation of the Joint Pretrial Order

Since the close of fact discovery, the Government has expanded the number of events it alleged to be kickbacks to as many as 526,144, and then most recently to approximately 154,000. In preparing for trial, NPC has endeavored to find witnesses who have relevant information about multiple events in this universe and who would agree voluntarily to testify. The witnesses at issue here will provide first-hand testimony about approximately 1,000 collective trigger events.<sup>9</sup> And are all witnesses who will provide similar testimony to the numerous other witnesses who NPC previously disclosed by name. While the Government cannot claim that it would have deposed these witnesses during fact discovery if it had known about them—after all, nearly all of the witnesses the Government deposed were witnesses that it had identified during its pre-intervention investigation to have relevant information, not witnesses NPC disclosed—NPC has repeatedly offered to make all 12 witnesses available for deposition since March 25, 2019, which provided the Government with ample time before trial.

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“Plaintiff’s initial or amended disclosures”, see id. Ex. 19 (Gov’t Amended Initial Disclosures, 8/17/16) at Ex. B. In addition the remaining five witnesses were included in NPC’s discovery responses and, thus, fall within the Government’s catchall provision in its disclosures, see supra n.7, which itself was incorporated by reference into NPC’s disclosures, see Gruenstein Opp’n MIL Decl., Ex. 17 at 6 (“(ii) identified by Plaintiffs in Plaintiffs’ initial or amended disclosures”).

<sup>9</sup> This includes 476 trigger events for Corinna Lee, 74 for Dr. Adam Rosenbluth, 7 for Dr. Rajeev Srivastava, 28 for Dr. Randall Zusman, 30 for Eileen Urban, 111 for Gail Christopher, 102 for Gairda Lauterbach-Hagan, 45 for Julie Brierley, 95 for Matthew Fragola, 36 for Michael Madix, and 33 for Stephen Boland. Paul Silverman, who was previously disclosed, did not participate in trigger events but will provide important testimony about, among other things, NPC’s use of STAR reports to try to encourage unique physician attendees at its events—testimony that became more probative following Dr. McMahon’s creation of the repeat attendance marker.



The Government has similarly included witnesses on its own list who have not been previously disclosed, and NPC has requested that it be allowed to depose those witnesses as well. Of the 127 witnesses on the Government's most recent list, 12 were not previously disclosed by name (although of those, 5 would fall within the broad "catch-all" disclosures that the Government, like NPC, included). The Government asserts that several of these witnesses—namely CMS, TRICARE and Federal Health Agency employees—are simply substitutions for previously disclosed witnesses who would have offered similar testimony. See Gov't MIL at 18 n.2. But the same is true of NPC's witnesses who, for example, are simply different sales representatives than the ones previously disclosed, but sales representatives nonetheless. In addition, another 33 of the 127 witnesses were previously disclosed by the Government on two disclosure lists with over 700 entries each, the lengths of which made it impossible for NPC to make informed decisions regarding discovery and trial preparation.<sup>10</sup> NPC has not sought to preclude the Government from calling any of these witnesses but rather requests the opportunity to depose them before trial.<sup>11</sup> See Sender v. Mann, 225 F.R.D. 645, 655 (D. Colo. 2004) (observing that the plaintiff's list of disclosures with hundreds of individuals left defendants with "the choice of either requesting a substantial number of additional depositions, with all of the attendant costs, or hoping that they correctly guessed which of the approximately 300 investors and brokers ultimately would testify at trial", and

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<sup>10</sup> In addition, while the two lists included individuals' addresses and phone numbers in some instances, the subjects of discoverable information were not listed for any of the witnesses, further inhibiting NPC's ability to use these disclosures to identify potential witnesses. See Fed. R. Civ. P. 26(a)(1)(A)(i).

<sup>11</sup> NPC has submitted a letter to the Court seeking leave to move to compel these depositions. April 22, 2019, Ltr. from R. Skaistis to Hon. P. Gardephe, ECF No. 324.



concluding that the appropriate remedy was to permit defendants to take post-discovery depositions of the individuals who would testify at trial).

D. The Proper Remedy Is Pre-Trial Depositions for Both Sides, Not Preclusion

The nature of this case, characterized by an enormous number of alleged trigger events, complicated and lengthy disclosures, and the Government's ever-changing theories, resulted in both parties disclosing certain witnesses only after the close of fact discovery. In NPC's case, this disclosure neither gives it an unfair advantage nor prejudices the Government. Rather, these witnesses are simply more likely to show up willingly to testify than others. Nearly all the additional witnesses are current employees whom NPC can bring to trial without the need to compel them, and doctors who are local and thus less likely to be inconvenienced by testifying. See supra note 5. In this situation, preclusion would be a drastic remedy; a more just remedy would be to allow both parties to take pre-trial depositions. See, e.g., City of Almaty, Kazakhstan v. Ablyazov, No. 115CV05345 (KHP) (AJN), 2019 WL 275701, at \*4 (S.D.N.Y. Jan. 22, 2019) ("preclusion of discovery is a drastic remedy that should be used only in cases where a different remedy cannot be crafted to minimize any prejudice to the party opposing the discovery"); Torres v. Dematteo Salvage Co. Inc., No. CV14774 (ADS) (AKT), 2016 WL 845326, at \*5 (E.D.N.Y. Mar. 2, 2016) (recognizing that any prejudice to plaintiffs caused by defendant disclosing a new expert witness in its JPTO "can be alleviated by allowing them to depose the expert prior to trial"); see also Sender, 225 F.R.D. at 655. As the Government notes in its motion, in determining whether to exclude evidence for failure to comply with disclosure obligations, courts consider the party's explanation for the noncompliant disclosure, the importance of the witness's testimony,

the potential prejudice to the opposing party, and the possibility of a continuance. Gov't MIL at 17 (citing Patterson v. Balsamico, 440 F.3d 104, 117 (2d Cir. 2006)) (excluding testimony of witnesses disclosed ten days before trial with no satisfactory explanation for the delay). Courts apply similar factors when considering requests to disclose additional witnesses before trial, including the diligence of the requesting party in conducting discovery within the guidelines of the Court, the foreseeability of the need for additional discovery and whether the non-moving party will be prejudiced.<sup>12</sup> See, e.g., City of Almaty, Kazakhstan, 2019 WL 275701, at \*4. Given the case history set forth above, and balancing all these factors including the potential prejudice on both sides, the correct result here is to permit both sides to take pre-trial depositions.

**6. The Government's MIL #6 To Exclude Parol Evidence Regarding the Meaning of 2010 Settlement Agreement**

Consistent with NPC's own MIL to preclude evidence and testimony regarding the 2010 Settlement and related corporate integrity agreement, NPC does not intend to introduce evidence at trial regarding the meaning of the 2010 settlement agreement.

**7. The Government's MIL #7—To Exclude Evidence and Argument Regarding Claims and Events Not Pursued at Trial—Should Be Denied**

Prior to April 1, 2019, the Government was pursuing damages for prescriptions written by all doctors who were purportedly "triggered" under Dr.

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<sup>12</sup> One of the factors courts consider is the imminence of trial. As noted, NPC has repeatedly offered to make the 12 witnesses available to the Government for deposition since March 25, 2019, with ample time for them to be deposed. In fact, NPC and the Government had preliminary discussions about arranging dates for these depositions during a meet and confer on March 25, and NPC followed up to do so on April 10 before the Government filed this motion.

McMahon's criteria. Then, as noted above, see supra § 5, on April 1, the Government informed NPC that it no longer intended to seek damages for "bribes provided through lunch n' learn events or bribes provided to doctors who (a) received less than \$1,000 in total remuneration from Novartis or (b) were national key opinion leaders". Gruenstein Decl. Supp. MILs Ex. 6. Having dropped claims arising out of these alleged bribes, the Government now seeks to preclude NPC from "refer[ring] at trial to previous versions of Plaintiffs' sham events list or to claims that were asserted earlier by Plaintiffs but which will not be presented to the jury". Gov't MIL at 23. While NPC does not intend to refer to "previous versions of Plaintiffs' sham events lists", there is no basis to preclude NPC from "refer[ring] at trial" to claims that the Government no longer intends to pursue.

First, as NPC showed in its Motion in Limine to Exclude Lunch-n-Learns and Payments Reimbursed Through Rebates from the Government's Computation of Damages (ECF No. 308), and contrary to the Government's assertion that it "elected not to pursue at trial claims for lunch and learn events", Gov't MIL at 23, the Government's damages calculation currently includes thousands of Lunch-n-Learns. Until the Government agrees to remove those events from its damages calculation, NPC must be in a position to argue that Lunch-n-Learns are not kickbacks.

Second, the Government's expert, Dr. McMahon, has testified that events could not have educational value for attendees if the attendees (1) attended three or more programs regarding the same drug within six months; (2) spoke at a program on a drug and subsequently attended an event regarding the same drug within six months; or (3) attended three or more programs in twelve months with a per-person meal cost of \$125 or more, see McMahon Rep. ¶ 54, which includes events that the Government now

says are no longer part of its claim for damages. NPC is entitled to question Dr. McMahon about the basis for his opinion, including, for example, his conclusion that many KOLs received bribes by virtue of their attendance at speaker program events. NPC will cross-examine Dr. McMahon about his basis for concluding that KOLs, some of the most respected medical doctors in the country, received bribes and will argue to the jury that his methodology is, among other things, overbroad, and thus flawed. That the Government no longer seeks damages for alleged bribes paid to certain of those KOLs does not immunize Dr. McMahon's methodology from attack; if anything, it suggests a weakness that must be probed at trial.<sup>13</sup>

8. **The Government's MIL #8—To Admit Evidence Regarding Lack of Consequences for a High Prescribing Novartis Speaker Who Sexually Assaulted a Sales Representative—Should Be Denied**

The Government has moved in limine to admit evidence that (i) Dr. Chris Vansickle, who the Government alleges was a frequent recipient of NPC bribes, became intoxicated at an NPC speaker event and stuck his tongue in the ear of a female NPC sales representative, and (ii) NPC took no action against Dr. Vansickle after the representative complained about the incident. See Gov't MIL at 24. Pursuant to Rule 403, the Government's motion should be denied because the prejudicial nature of a highly inflammatory allegation of sexual assault outweighs any minimal probative value.

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<sup>13</sup> The Government cites several cases where courts precluded parties from introducing evidence of claims that were withdrawn or rejected at summary judgment. Gov't MIL at 23-24. Those cases are inapposite because the parties could not put forward any plausible argument that the withdrawn or rejected claims at issue remained relevant, whereas here the withdrawn claims are clearly still relevant because the Government's expert is testifying about them.

First, accusations of sexual assault are highly inflammatory and admitting evidence of Dr. Vansickle's alleged behavior would cause undue prejudice to NPC. Cf. L-3 Commc'ns Corp. v. OSI Sys., Inc., No. 02 CIV. 9144 (PAC), 2006 WL 988143, at \*8 (S.D.N.Y. Apr. 13, 2006) ("[T]he naked presentation of [a sexual harassment charge against a defense witness] may be of a sufficiently inflammatory or prurient nature to be significantly prejudicial to [defendant]. . . . Because evidence regarding allegations of sexual harassment are highly prejudicial, [plaintiff] may not examine [the witness] on that issue. Fed. R. Evid. 403."); Smith v. Airborne Freight Corp., 96 F.3d 1451, at \*6 (9th Cir. 1996) ("This is weighed against the highly prejudicial nature of [witness] O'Neal's testimony. Her testimony involved claims of sexual harassment against [defendant's] drivers. This aspect of her testimony undoubtedly had far more impact than O'Neal's inexact testimony about the handling of her complaint . . . ." (emphasis in original)).

Second, the evidence at issue is of minimal probative value because the Government is not seeking to admit it to show that this one doctor received a kickback, but, rather, to illustrate generally "the party atmosphere of the NPC speaker events" and that NPC "was fanatical about keeping its high-prescribing physicians happy". See Gov't MIL at 25. For purposes of these broad-stroke arguments, one alleged incident has little probative value. NPC also does not oppose the Government introducing evidence, if any, that drinking occurred at the event, further diminishing the incremental probative value of Dr. Vansickle's alleged conduct.

This evidence further lacks probative value because, as the Government contends in its motion, it is cumulative of other evidence about the circumstances of



speaker events that the Government plans to use and does not change the overall mix of information available. See Gov't MIL at 25 ("Other evidence at the trial will demonstrate the party atmosphere of the NPC speaker events, including evidence that approximately 75 events were held at Hooters. The incident involving [the sales representative] and Dr. Vansickle is part of the overall picture . . . ."); see also McCallum, 584 F.3d at 477 ("[T]he availability of other, less prejudicial, evidence on the same point ordinarily reduces the probative value of a given item of extrinsic evidence . . . . If the incremental value is slight, and the possibility of prejudice through misuse by the jury great, the court should exclude the evidence under Rule 403.") (quoting 2 Weinstein, Federal Evidence § 404.21 (Joseph M. McLaughlin, Ed., Matthew Bender & Co. 2009)); Park West Radiology v. CareCore Nat. LLC, 675 F. Supp. 2d 314, 325 (S.D.N.Y. 2009) (excluding evidence under Rule 403 as "unnecessary" where non-movant "will have ample opportunity at trial to present other evidence to the jury on the question").

Allowing the Government to introduce evidence of Dr. Vansickle's alleged behavior is therefore unnecessary and gratuitously prejudicial.

**9. The Government's MIL #9—To Admit Documents Concerning CafePharma Posts—Should Be Denied**

The Government has moved in limine to admit four email chains in which Novartis compliance employees copied and internally circulated anonymously written posts from CafePharma, an online messaging board for the industry, and discussed how to respond to the posts. See Gov't MIL at 26; Vargas Decl. Exs. P, Q, R, S. The Government's motion should be denied pursuant to Rules 802 and 403.

The Government contends in its motion that it "offers these posts only to show the compliance department's awareness of the allegations and its response to

them”. See Gov’t MIL at 27. This assertion is disingenuous, because the Government has already shown this awareness with other evidence, and NPC does not contest it. As the Government expressly points out in its motion, Julie Kane, a witness NPC intends to call at trial, has already testified that “compliance personnel reviewed CafePharma as a ‘form of monitoring’ for compliance violations . . . and testified that the posts ‘meant we needed to continue to do our hard work to manage the programs.’” See id. (referencing Vargas Decl., Ex. T (Dep. Tr. of Julie Kane at 108:17-109:9; 267:13-268:18)); see also Gruenstein Opp’n MIL Decl., Ex. 20 (Dep. Tr. of Julie Kane at 178:3-180:12). NPC concedes that there were anonymous posts on CafePharma and—as reflected in the emails that the Government seeks to admit—that Compliance responded to them.

Given Ms. Kane’s anticipated testimony and NPC’s concession, the only possible reason the Government seeks to admit these anonymous posts into evidence is for their substance. As such, the posts are hearsay and inadmissible under Rule 802. Moreover, regardless of whether the Government genuinely intends to admit the posts solely to show the compliance department’s awareness and its response to them, these posts are more prejudicial than probative and should not be admitted, pursuant to Rule 403.

**10. The Government’s MIL #10—To Exclude Evidence and Argument Contrary to the Government’s Suggested Causation Standard—Should Be Denied**

The Government has moved in limine to exclude evidence and argument contrary to the “proper causation standard”—that is, “evidence that doctors did not change their prescribing behavior in response to Novartis kickbacks”. Gov’t Trial Mem. at 27. This motion is duplicative of the Government’s first MIL and should be denied for the same reasons. See supra § 1. As NPC showed in response to that motion and in its

pretrial memorandum of law, Def.'s Pretrial Mem. at 3-7, the Government must prove causation to prevail on its claims at trial. Accordingly, evidence related to causation (among other elements), including, without limitation, evidence that doctors did not change their prescribing behavior in response to NPC's alleged kickbacks is plainly relevant.<sup>14</sup>

The Government's argument that it does not need to prove causation at trial—that is, that it does not need to prove that NPC's bribes caused doctors to prescribe NPC medications—is legally incorrect. The Government, in essence, makes two fundamental points related to causation in its motions in limine and its pretrial memorandum of law: First, the Government recognizes that it must show a link between a kickback and the submission of a claim, but contends that the only link it needs to show is that a claim followed a kickback. See, e.g., Gov't Trial Mem. at 3. Chronology is not causation, however, and NPC demonstrated why this theory is legally incorrect in its pretrial memorandum of law. Def.'s Pretrial Mem. at 2-7.

Second, the Government contends that a violation of the AKS by NPC alone—not NPC and the doctors—is sufficient to establish liability under the FCA. See

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<sup>14</sup> In its pretrial memorandum of law, the Government notes that “the AKS does not require a kick-back scheme to succeed in generating new business (i.e., new patient prescriptions) in order for a violation to have occurred”. Gov't Trial Mem. at 5 (internal quotation marks omitted) (citing United States ex rel. Arnstein v. Teva Pharms. USA, Inc., No. 13-cv-3702 (CM), 2016 WL 750720, at \*17 (S.D.N.Y. Feb. 22, 2016)). NPC does not dispute that the Government can establish liability without proving incremental prescriptions, as a kickback could still be a substantial factor in a doctor's prescribing decisions without actually succeeding in increasing prescriptions. See supra § 1.A. However, as discussed in response to MIL #1 and in NPC's pretrial memorandum of law, the Government may only recover damages for NPC prescriptions written because of alleged kickbacks. See id.; Def.'s Pretrial Mem. at 15-16.

Gov't Trial Mem. at 4 (“The AKS ensures that doctors’ decision-making is based solely on the medical needs of their patients, and is not potentially affected by financial consideration.” (emphasis added) (citing United States v. Patel, 778 F.3d 607, 612 (7th Cir. 2015))); id. (A “kickback creates the very real possibility that the recipient’s medical decisions were not based entirely on his or her independent medical judgment, but (in whole or in part) on the kickback.” (emphasis added)). If a claim is not actually false—if a doctor rejected or did not even know of a bribe, and wrote a prescription solely based on his independent medical judgment—then NPC cannot be said to have caused a false claim to be submitted. See Def.’s Pretrial Mem. at 8-14.

In addition, Patel, on which the Government relies for its proposition that “[t]he AKS ensures that doctors’ decision-making is based solely on the medical needs of their patients, and is not potentially affected by financial consideration”, Gov’t Trial Mem. at 4, is a criminal AKS case that does not involve the FCA, see 778 F.3d 607. As described in NPC’s pretrial memorandum of law, the Government must prove causation here because (among other reasons) this is not merely an AKS case—instead, it is a case where the Government is seeking to use an AKS violation as a predicate for an FCA claim and so a kickback offer is not enough. Indeed, in Teva II, Judge McMahon recognized that causation must be proven where, as here, a plaintiff seeks to use an alleged AKS violation as a predicate for an FCA claim. 2019 WL 1245656, at \*27 (finding that relators had “raised an inference of causation . . . that a jury may use to find liability” (emphasis added)); supra § 1.A.

The Government also relies on Greenfield in support of its position regarding causation. For the reasons already discussed in response to MIL #1 above,



supra § 1, Greenfield addresses a different issue than is present here and was present in Teva II: NPC, like Teva, was not in the prescribing chain and so can only be liable under the “cause[d] to be presented” prong of the FCA, which by its explicit terms requires a showing of causation, as Judge McMahon recognized. Moreover, Teva II, unlike Greenfield, looks beyond summary judgment and explains that at trial a jury must ultimately find causation to impose liability. See Teva II, 2019 WL 1245656, at \*24-27.<sup>15</sup>

In any event, as noted in response to MIL #1, evidence of whether doctors changed their prescribing behavior in response to alleged kickbacks is probative not only of causation but also of NPC’s state of mind and of whether the promotional programs at issue constituted kickbacks at all.

**11. The Government’s MIL #11—To Exclude Evidence and Argument Concerning the Fair Market Value for Speaker Services—Should Be Denied**

The Government has moved in limine to exclude evidence of the fair market value of honoraria paid to speakers who gave presentations at NPC speaker

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<sup>15</sup> The Government also cites a motion to dismiss decision, United States ex rel. Bawduniak v. Biogen Idec, Inc., No. 12-CV-10601-IT, 2018 WL 1996829, at \*1 (D. Mass. Apr. 27, 2018), and an appeal of a motion to dismiss decision, U.S. ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 298 (3d Cir. 2011), in support of its position on causation. While “allegations that ‘Defendant paid kickbacks to [specific] physicians . . . to induce those physicians to prescribe particular medications, and that the physicians then prescribed those medications, causing claims to be submitted to Medicare and Medicaid’” may be sufficient to survive a motion to dismiss in the First Circuit, as Biogen holds, 2018 WL 1996829, at \*6, Judge McMahon noted in Teva II that more (namely, causation) ultimately must be proven at trial, see supra § 1.A; Def.’s Pretrial Mem. at 6-7. Wilkins is also inapposite. The defendant in Wilkins submitted claims for payment directly to a government healthcare program while allegedly providing kickbacks to physicians, and itself certified compliance with all applicable healthcare laws. 659 F.3d at 300-301. Thus, Wilkins, like Greenfield, does not take into account the “cause[d] to be presented” language in the FCA.



programs, even though the Government contends that such payments constituted bribes to the speakers in violation of the AKS.<sup>16</sup> According to the Government, evidence concerning the fair market value of honoraria for speaking at those programs “is irrelevant here, given that the Government has not asserted that Novartis paid doctors above market for bona fide speaker events”, but rather has asserted that “Novartis used sham events to funnel cash speaking fees to ‘speakers’ in an attempt to induce them to prescribe Novartis drugs.” Gov’t MIL at 28; see Gov’t Trial Mem. at 9-11. But the Government’s allegations and current characterization of NPC’s conduct do not bind NPC, which is entitled to defend itself by offering evidence that it paid speakers fairly for the legitimate services they provided at NPC promotional events.

Significantly, the Government’s requested relief is inconsistent with its burden under the AKS to prove that the honoraria that NPC offered doctors constituted “remuneration” by reference to the fair market value of those payments. The AKS prohibits any person from knowingly or willfully “offer[ing] to pay any remuneration . . . to any person to induce such person . . . to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program.” 28 U.S.C. § 1320a-7b(b)(2)(A). Remuneration, in turn, is defined to include “transfers of items or services for free or for other than fair market value.” 42 U.S.C. § 1320a-7a(i)(6) (emphasis

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<sup>16</sup> See Joint Proposed Instr. A-2 (“According to Plaintiffs, these bribes came in different forms, including cash payments, called honoraria, which Novartis paid to doctors who were hired to speak at their programs, as well as expensive meals, alcohol, gifts, and entertainment.”); Joint Proposed Instr. D-1 (“Plaintiffs allege in this lawsuit that between January 2002 and November 2011, Novartis offered or paid illegal bribes to doctors in the form of honoraria, meals, gifts and entertainment in order to get those doctors to prescribe Novartis medications.”).

added). It follows that “[t]o prove that a defendant offered or paid remuneration, the plaintiff must compare the contracted rates with fair market value.” Bingham v. Baycare Health Sys., No. 8:14-cv-73-T-23JSS, 2016 WL 8739056, at \*6 (M.D. Fla. Dec. 16, 2016); accord United States ex rel. Fair Lab. Pracs. Assocs. v. Quest Diagnostics Inc., No. 05 Civ. 5393 (RPP), 2011 WL 1330542, at \*2 (S.D.N.Y. Apr. 5, 2011) (“The AKS defines ‘remuneration’ as including ‘transfers of items or services for free or for other than fair market value.’” (citation omitted)), aff’d, 734 F.3d 154 (2d Cir. 2013); Klaczak v. Consol. Med. Transp., 458 F. Supp. 2d 622, 678-79 (N.D. Ill. 2006) (“In the context of the [AKS], courts use ‘fair market value’ as the gauge of value when assessing the remuneration element of the offense.”).

For example, in United States ex rel. Brown v. Celgene Corp., 226 F. Supp. 3d 1032 (C.D. Cal. 2016), the court granted summary judgment on FCA claims in favor of a pharmaceutical manufacturer, where, as here, the Government alleged that honoraria paid by the manufacturer to speakers were instead bribes to induce the speakers to prescribe the defendant’s medicines in violation of the AKS. As the court explained, summary judgment was warranted because the defendant’s honoraria payments were not “excessive compared to the honoraria provided by other physician speaker programs”. Id. at 1054.

The Government attempts to distinguish Brown by relying on details supporting the Brown court’s summary judgment determination, such as the absence of fact issues concerning appropriate venues. Gov’t Trial Mem. at 9-10. Those distinctions are irrelevant here because NPC is not seeking summary judgment, but rather is seeking to defend itself at trial against the Government’s allegations that honoraria were bribes by

arguing that NPC paid doctors fair market value for services provided. Indeed, under the AKS, the Government's contention that NPC's honoraria payments to speakers constituted "remuneration" in violation of the AKS necessarily requires the jury to consider the fact question of whether those payments were "excessive", i.e., whether the payments exceeded fair market value. Brown, 226 F. Supp. 3d at 1054.

Equally unavailing is the Government's attempt to distinguish the authorities that NPC cites in its proposed jury charges on the ground that the "alleged bribe[s in those cases] took the form of an overpayment or an undercharge". Gov't Trial Mem. at 10-11. That is precisely how the Government has characterized honoraria that NPC paid to speakers in this case. For example, in its opposition to NPC's motion for summary judgment, the Government variously referred to "massive speaker fees", "substantial honoraria" and "high honoraria". See Mem. of Law in Opp'n to Def.'s Mot. for Summ. J., ECF No. 230, at 1, 2, 9 (emphasis added). And one of the Government's experts, Dr. McMahon, opined in his report that one of the "indicia" that NPC speaker programs "lack[ed] educational value or purpose" was the "excessive compensation" paid to speakers. McMahon Rep. ¶¶ 86-91 (emphasis added). The Government's and Dr. McMahon's use of these descriptors suggests that the Government intends to introduce evidence that the honoraria NPC paid to speakers was "massive", "substantial", "high" or "excessive"—in other words, that they exceeded fair market value. NPC should be permitted to rebut that argument.

In any event, the Government's position on this motion—"that the speaker and roundtable events were shams and that NPC was simply providing cash and extravagant meals to doctors to induce them to prescribe Novartis drugs", Gov't Trial

Mem. at 9—is just another way of saying that the fair market value of the services provided by the participating doctors was zero, and, therefore, that the honoraria payments in their entirety constituted overpayments. Whichever position the Government ultimately takes at trial, NPC is entitled to rebut the Government’s argument with evidence that it paid honoraria in amounts consistent with the fair market value of the services provided by speakers at its programs.

Even aside from the Government’s affirmative burden to prove the element of remuneration, as the Government acknowledges, the AKS expressly provides a safe harbor for personal services and management contracts. See 42 C.F.R. § 1001.952(d); Def.’s Proposed Instr. D-11; Gov’t Trial Mem. at 11. That provision states that “‘remuneration’ does not include any payment made by a principal to an agent” if certain conditions are met, including that “[t]he aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.” 42 C.F.R. § 1001.952(d)(5) (emphasis added). Thus, the fair market value of the services that speakers provided to NPC is also an element of the safe harbor defense that NPC intends to present and the jury will have to consider.

**12. The Government’s MIL #12—To Preclude Argument that NPC Is Only Liable for the Conduct of Employees “with Authority”—Should Be Denied**

The Government’s MIL #12 proceeds from the false premise that NPC seeks to limit liability to acts of its “managers or senior executives”. Gov’t MIL at 28. NPC does not dispute “that an employer is liable under the FCA for the conduct of any

employee acting within the scope of his or her employment.” Id. However, it is well settled that, under the FCA, “‘collective knowledge’ provides an inappropriate basis for proof of scienter.” United States v. Science Applications Int’l Corp., 626 F.3d 1257, 1274 (D.C. Cir. 2010). In other words, the Government cannot allege a vast nationwide scheme to defraud and then seek to “‘prove scienter by piecing together scraps of ‘innocent’ knowledge held by various corporate officials, even if those officials never had contact with each other or knew what others were doing in connection with a claim seeking government funds’”. Id. at 1275 (citation omitted).

The Government does not dispute the foregoing legal principle regarding “collective knowledge”. Instead, the Government contends that the legal principle does not apply in this case because “the Government will present evidence that numerous NPC employees acting within the scope of their employment knowingly and willfully provided kickbacks to doctors and thereby knowingly caused false claims to be submitted to federal health care programs for NPC drugs that these doctors later wrote.” Gov’t Trial Mem. at 15. The Government’s characterization of the evidence constitutes argument relating to a fact issue for a properly instructed jury to resolve. What the Government claims it will prove cannot be a basis for excluding contrary rebuttal evidence, and does not obviate the need for the Court to instruct the jury properly on the law. Accordingly, the Government’s MIL #12 should be denied.

**13. The Government’s MIL #13—To Exclude Evidence and Argument as to Whether Novartis Specifically Intended a Government Health Care Program to Pay for Prescriptions Resulting from Bribes—Should Be Denied**

In MIL #13, the Government seeks to exclude evidence and argument about whether NPC knew that a Government health care program would make payments



for prescriptions resulting from NPC's alleged violations of the AKS. The Government's motion ignores the fundamental elements of its FCA claims and misconstrues the AKS.

The Government asserts claims under the FCA, rather than directly under the AKS, which does not provide for civil liability. The FCA provides for civil liability against any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the Government. 31 U.S.C. § 3729 (a)(1)(A). Federal law provides that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]". 42 U.S.C. § 1320a-7b(g). But nothing in federal law obviates the need for the Government to prove, under the FCA, that NPC "knowingly" caused a false or fraudulent claim "to be presented" to the Government. See United States ex rel. Sterling v. Health Ins. Plan of Greater New York, Inc., No. 06 Civ. 1141 (PAC), 2008 WL 4449448, at \*3 (S.D.N.Y. Sept. 30, 2008) ("Presentment of the false claim to the United States Government is a requirement of subsection (a)(1)."). To prove that element, the Government must show that NPC had "actual knowledge" or acted in "deliberate ignorance" or "reckless disregard" about whether false or fraudulent claims were being submitted to the Government. 31 U.S.C. § 3729(b)(1)(A). The Government cannot satisfy this burden without showing that NPC knew prescriptions would be presented to Government health care programs.

In any event, even aside from the elements of the FCA, the Government misconstrues the AKS, which independently requires the Government to prove that NPC intended that false claims be presented to the Government as distinct from private payors. In United States ex rel. King v. Solvay Pharms., Inc., 871 F.3d 318 (5th Cir. 2017), the

court held that “[b]ecause AKS liability is limited to prescriptions that were reimbursed by the government, not private parties, satisfying the scienter requirement of ‘willfully’ requires evidence indicating that Solvay intended Medicaid to pay for these prescriptions.” Id. at 322 n.12 (internal citation omitted). The court affirmed summary judgment on behalf of the defendant where “it would be speculation to infer that Solvay specifically intended such prescriptions to be reimbursed by Medicaid.” Id.<sup>17</sup>

Thus, the applicable statutes and case law plainly require proof that NPC knew that Government health care programs would pay for prescriptions resulting from alleged bribes. Absent such proof, there would be nothing but “speculation to infer that [NPC] specifically intended such prescriptions [written by doctors who attended speaker or roundtable programs] to be reimbursed” by the Government. King, 871 F.3d at 322 n.12.

**14. The Government’s MIL #14 To Exclude Reference to Treble Damages and Civil Penalties**

NPC does not anticipate referring to treble damages or civil penalties at trial.

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<sup>17</sup> The Government contends that King is inconsistent with the Fifth Circuit’s previous decision in United States v. Miles, 360 F.3d 472 (5th Cir. 2004). Gov’t Trial Mem. at 16 n.2. To the contrary, King and Miles are consistent. In Miles, the court stated that the AKS “criminalizes the payment of any funds or benefits designed to encourage an individual to refer another party to a Medicare provider for services to be paid for by the Medicare program”. Id. at 479. The court held that there was no issue whether the defendants’ payments to a public relations firm were for services to be paid by Medicare because those payments “were based on the number of Medicare patients that [defendants] secured from [the public relations firm’s] activities”. Id. at 480. The court nevertheless reversed the defendants’ convictions because the payments “were not made to the relevant decisionmaker as an inducement or kickback for sending patients”. Id.

**CONCLUSION**

For the foregoing reasons, NPC respectfully requests that the Court deny the Government's motions on their merits or, in the instances where NPC does not intend to offer the challenged evidence, as moot.

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Respectfully submitted,

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